

REMARKS

Status of the Claims

Claims 1, 5, 7-18, 22-25, 27, 31-33, 35, 37 and 43-54 were pending. Claims 1, 5, 7-18, 22-25, 27, 31-33, 35, 37 and 43-54 have been canceled without prejudice or disclaimer. Applicants respectfully reserve the right to pursue subject matter of the application as filed in a subsequent application(s) such as a divisional or continuation application. New claims 55-64 have been added. No new matter has been added. Claims 55-64 are currently under examination.

Claims Amendments

Claims 55-64 have been added. Support for these claims can be found throughout the application but at least at page 4 lines 15-19 and 30-32; page 5 lines 1-3 and 28-29; page 7 lines 27-30; page 8, lines 17-33; page 10, lines 31-33; page 11 lines 1-2; page 12 lines 1-17; page 15 lines 15-33; page 16 lines 1-22; and page 29 lines 15-25 of the application as originally filed.

Rejection under 35 U.S.C. §102, maintained

§102(e)

On page 2, the Action asserts that “Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Gissman et. al (U.S. Patent no. 7,371,391 B2, [hereinafter, “Gissmann”])...Gissmann et al taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere...”

The Applicants respectfully submit that new claims 55-64 overcome rejections based on Gissmann. Gissman recites “Vaccine formulations comprising viral capsomeres...Therapeutic and prophylactic methods of use for the vaccine formulations...” (see Abstract). Gissmann fails to disclose “A *complex* having two polypeptide molecules comprising...a first polypeptide molecule having five papillomavirus capsid L1 polypeptides or truncated papillomavirus capsid L1 polypeptides; and ... a second polypeptide molecule comprising at least one immunogenic epitope and one or more papillomavirus capsid L1 interaction sequences” elements of new independent claim 55. Gissman fails to disclose a complex having a 5:1 ratio of five papillomavirus capsid L1 polypeptides to a second polypeptide. Gissman is directed toward chimeric proteins not a complex of proteins that *non-covalently* associate as in the instant case. Therefore, the Applicants respectfully request removal of the rejection.

On pages 3-4, the Action asserts that “Claims 37, 43, 50, 52-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et. al (U.S. Patent no. 6,908,613 B2) [hereinafter, “Wilson”] ...for the reasons of record...under inherency doctrine...” The Applicants respectfully disagree with this rejection.

The Applicants respectfully submit that new claims 55-64 overcome rejections based on Wilson. The Applicants submit that Wilson recites “A *chimeric* HPV L1 protein comprising HPV-18 L1 protein and HPV-45 L1 protein” (see independent claim 1) and “A method of treating papillomavirus caused by at least one of HPV-18 and HPV-45 comprising administering to a patient an effective amount of the [chimeric] protein of claim 1” (see claim 5 of Wilson). Wilson fails to disclose “A *complex* having two polypeptide molecules comprising...a first polypeptide molecule having five papillomavirus capsid L1 polypeptides or truncated papillomavirus capsid L1 polypeptides; and ... a second polypeptide molecule comprising at least one immunogenic epitope and one or more papillomavirus capsid L1 interaction sequences” elements of new independent claim 55. Wilson fails to disclose a complex having two polypeptides where the first polypeptide has five polypeptides derived from papillomavirus capsid L1 polypeptides or truncated forms thereof and the second polypeptide has one or more L1-interaction sequences. Therefore, the Applicants respectfully request removal of the rejection.

On pages 4-5, the Action asserts that “Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Hallek et. al (U.S. Patent no. 7,182,947 B2, [hereinafter, “Hallek”]) for the reasons of record...Hallek et al taught *chimeric* protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere.”

The Applicants respectfully submit that new claims 55-64 overcome rejections based on Hallek. The Applicants submit that Hallek recites “Vaccine formulations comprising viral capsomeres are disclosed along with methods for their production...” (see Abstract). Hallek recites “A protein encoded by an...encoding a truncated HPV L1 protein... wherein said protein is immunogenic against HPV,” (see independent claim 1 of Hallek). Hallek recites in claim 2 “A protein encoded by...encoding a fusion protein, said fusion protein comprising an amino acid sequence of a truncated first HPV L1 and an amino acid sequence of a second HPV proteins...said second HPV protein is selected from the group consisting of E1, E2...” Hallek recites in claim 5, “A protein of claim 2 wherein said HPV protein is an HPV E7 protein.” The Applicants respectfully submit that Hallek recites “the second protein be selected from the group

E1, E2, E3, E4, E%, E6, and E7-early gene products encoded in the genome of papilloma virus strains HVP6...” (see Hallek column 4 lines 22-27). Hallek fails to disclose “A *complex* having two polypeptide molecules comprising...a first polypeptide molecule having five papillomavirus capsid L1 polypeptides or truncated papillomavirus capsid L1 polypeptides; and ... a second polypeptide molecule comprising at least one immunogenic epitope and one or more papillomavirus capsid L1 interaction sequences” elements of new independent claim 55. Hallek fails to disclose a complex having a 5:1 ratio of papillomavirus capsid L1 polypeptides or truncated polypeptides to a second polypeptide with one or more papillomavirus capsid L1 interaction sequences. Therefore, the Applicants respectfully request removal of the rejection based on Hallek.

Rejection under 35 U.S.C. §102, maintained

§102(b)

On page 5, the Action asserts that “Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Gissman et. al (U.S. Patent no. 6,228,368 B1) [hereinafter, “Gissmann2”] for the reasons of record...Gissmann et al taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere (see abstract, and claims 1-14)...Moreover, the ratio of 1 to 5 has no patentable weight...There is nothing in the record to show the product disclosed by Gissman is any different than the product now claimed...” The Applicants respectfully disagree with this assertion.

The Applicants respectfully submit that new claims 55-64 overcome rejections based on Gissmann2. Gissmann2 fails to disclose “A *complex* having two polypeptide molecules comprising...a first polypeptide molecule having five papillomavirus capsid L1 polypeptides or truncated papillomavirus capsid L1 polypeptides; and ... a second polypeptide molecule comprising at least one immunogenic epitope and one or more papillomavirus capsid L1 interaction sequences” elements of new independent claim 55. Gissman2 fails to disclose a complex having a 5:1 ratio of papillomavirus capsid L1 polypeptides or truncated polypeptides to a second polypeptide with one or more papillomavirus capsid L1 binding regions.

In addition, the Applicants respectfully submit the following excerpts from the application as filed:

Bridging paragraph pages 4-5 where the Applicants recite “The complexes may be provided as capsomeres with a stoichiometry of 1 chimeric protein to 5 papilloma capsid L1 polypeptides. Alternatively these complexes may provide immunogenic epitopes at a stoichiometry of 1 to 5 papilloma capsid L1 proteins.”

Bridging paragraph pages 10-11 where the Applicants recite “Complexes of the present invention will most preferably be in the form of a capsomere. Capsomeres of the present invention will generally have a stoichiometry of about one chimeric protein of the present invention to about five papillomavirus L1 capsid proteins...”

Page 29 lines 15-25, Example 10, recites “...The L1:L2 ratio in the resulting purified complexes was approximately 5:1. Thus, a single molecule of L2 associates with a pentamer of L1...”

The Applicants respectfully point to Appendix A (attached to this submission) where an exemplary recombinantly expressed complex (*e.g.* a 5:1 ratio of L1 to L2) is further described.

The Applicants have pointed to some of the evidence in the application as filed and Appendix A to rebut the assertion in the action regarding “the ratio of 1 to 5 has no patentable weight.” The Applicants submit that a complex having five papillomavirus L1 capsid polypeptides or truncated forms thereof and another different protein molecule having one or more papillomavirus L1 capsid interaction sequence is neither disclosed, suggested or rendered obvious by the recited art. All of the art recited in this and previous office actions concerned chimeric molecules, not a complex of two polypeptides molecules, where the polypeptide complex optionally, has as one component, a chimeric. Therefore, the Applicants respectfully request removal of the rejection based on Gissman2.

On page 6, the Action asserts that “Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcea et. al (U.S. Patent no. 6,,165,471 A) [hereinafter, “Garcea”]...There is nothing in the record to show the product disclosed by Garcea is any different than the product now claimed. Moreover, the ratio of 1 to 5 has no patentable weight...” The Applicants respectfully disagree with this rejection.

The Applicants respectfully submit that new claims 55-64 overcome rejections based on Garcea. The Applicants respectfully submit that Garcea recites “stable HPV capsomeres which express at least one virus-neutralizing conformational epitope of a native HPV L1 protein which are substantially capsomeres...”(see Abstract). Garcea fails to disclose “A *complex* having two polypeptide molecules comprising...a first polypeptide molecule having five papillomavirus

capsid L1 polypeptides or truncated papillomavirus capsid L1 polypeptides; and ... a second polypeptide molecule comprising at least one immunogenic epitope and one or more papillomavirus capsid L1 interaction sequences” elements of new independent claim 55. Garcea fails to disclose a complex that is not a chimeric, having a 5:1 ratio of five papillomavirus capsid L1 polypeptides or truncations thereof non-covalently associated with a second polypeptide molecule. Therefore, Garcea fails to disclose elements of new independent claim 55, of which claims 56-64 depend. The Applicants request removal of the rejection based on Garcea.

The Applicants respectfully submit that new independent claim 55 is in condition for allowance. Because claims 56-64 depend from and contain all the elements of new independent claim 55 plus additional elements, claims 56-64 are also in condition for allowance.

CONCLUSION

For at least the reasons stated above, the Applicants respectfully submit that new claims 55-64 are in condition for allowance. Please feel free to call the undersigned, if additional response is required.

Respectfully submitted,

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